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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,874	07/31/2003	Indranil Nandi	G-33302P1	1795

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NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
HENRY, MICHAEL C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 09/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

S.D.O

Office Action Summary	Application No.	Applicant(s)	
	10/631,874	NANDI ET AL.	
	Examiner	Art Unit	
	Michael C. Henry	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *05/19/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-20 are pending in application

Information Disclosure Statement

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5, 10, 11, 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakajima et al. (JP 09315971 A2, September 12, 1997 (Abstract only)).

In claim 1, applicant claims "A pharmaceutical composition comprising fexofenadine or a pharmaceutical acceptable salt thereof, about 10 wt. % to about 70 wt. % of lactose, and about 1 wt. % to about 40 wt. % of a low-substituted hydroxypropyl cellulose, wherein the weight percents are based on the total weight of the pharmaceutical composition." Nakajima et al. disclose applicant's pharmaceutical composition comprising fexofenadine or a pharmaceutical acceptable salt thereof, about 27 wt. % of lactose, and about 10 wt. % of a low-substituted hydroxypropyl cellulose, wherein the weight percents are based on the total weight of the pharmaceutical composition (see abstract, English Translation, Example/[0010]). Dependent claims 3-5, 10, 11, 16, 17 which are drawn to a pharmaceutical composition wherein the

fexofenadine, lactose or low-substituted hydroxypropyl cellulose of specific wt. % range, is also anticipated by Nakajima et al., since Nakajima et al.'s composition also contains the same wt.% of fexofenadine, lactose or low-substituted hydroxypropyl cellulose (see abstract).

In claim 18, applicant claims "A method of preparing a pharmaceutical composition comprising fexofenadine or a pharmaceutical acceptable salt thereof, about 10 wt. % to about 70 wt. % of lactose, and about 1 wt. % to about 40 wt. % of a low-substituted hydroxypropyl cellulose, wherein the weight percents are based on the total weight of the pharmaceutical composition, said method comprising:

(a) mixing fexofenadine, lactose, low-substituted hydroxypropyl cellulose, and optionally one or more excipients to form a premix;

(b) adding a solvent and optionally a surfactant to the premix formed in Step (a) to form a wet granulation; and

(c) drying the wet granulation to form dried granules;

(d) optionally milling the dried granules; and

(e) mixing at least one excipient with the dried granules to form a pharmaceutical composition." Nakajima et al. disclose applicant's method of preparing a pharmaceutical composition comprising fexofenadine, lactose, and a low-substituted hydroxypropyl cellulose, said method comprising: (a) mixing fexofenadine, lactose, low-substituted hydroxypropyl cellulose, and other excipients to form a premix; (b) adding a solvent (purified water) to form a wet mixture; and (c) drying the wet mixture; (d) milling the dried mixture; and (e) mixing an excipient (magnesium stearate) with the dried mixture to form a pharmaceutical composition (see abstract, English Translation, Example/[0010]). It should be noted that the examiner considers

the dried mixture to be granules or in granular form, since Nakajima et al. disclose that the mixture was sieved and regulated for particle size (see abstract, English Translation, Example/[0010]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 6-9, 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakajima et al. (JP 09315971 A2, September 12, 1997 (Abstract only)).

In claim 1, applicant claims "A pharmaceutical composition comprising fexofenadine or a pharmaceutical acceptable salt thereof, about 10 wt. % to about 70 wt. % of lactose, and about 1 wt. % to about 40 wt. % of a low-substituted hydroxypropyl cellulose, wherein the weight percents are based on the total weight of the pharmaceutical composition." Dependent claims 2,6-9, 12, 13 are drawn to specific wt. % and mg of the components of said composition. Claims 14-17 are drawn to low-substituted hydroxypropyl cellulose of specific average particle sizes and wt. %.

Nakajima et al. disclose applicant's pharmaceutical composition comprising fexofenadine or a pharmaceutical acceptable salt thereof, about 27 wt. % of lactose, and about 10 wt. % of a

low-substituted hydroxypropyl cellulose, wherein the weight percents are based on the total weight of the pharmaceutical composition (see abstract, English Translation, Example/[0010]).

The difference between applicant's claimed composition and the composition disclosed by Nakajima et al. is that applicant's composition contains different amounts (e.g., mg), wt. %, and Nakajima et al. do not disclose the type of low-substituted hydroxypropyl cellulose used in in the composition. However, the use of specific quantities (e.g., mg), wt. % and type of low-substituted hydroxypropyl cellulose of said composition depends on the need, such as the individual to which this composition is administered.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Nakajima et al., to have prepared a pharmaceutical composition comprising fexofenadine, lactose and hydroxypropyl cellulose of different quantities (e.g., mg), wt. % and types of low-substituted hydroxypropyl cellulose to be used as an antihistamine composition, depending on need, such as the severity of the illness treated and the age and weight of the individual treated.

One having ordinary skill in the art would have been motivated in view of Nakajima et al., to prepare a pharmaceutical composition comprising fexofenadine, lactose and hydroxypropyl cellulose of different quantities (e.g., mg), wt. % and types of low-substituted hydroxypropyl cellulose to be used as an antihistamine composition, depending on need, such as the severity of the illness treated and the age and weight of the individual treated.

In claim 19, applicant claims "A method of preparing a pharmaceutical composition comprising fexofenadine or a pharmaceutical acceptable salt thereof, about 10 wt. % to about 70 wt. % of lactose, and about 1 wt. % to about 40 wt. % of a low-substituted hydroxypropyl

cellulose, wherein the weight percents are based on the total weight of the pharmaceutical composition, said method comprising:

(a) mixing fexofenadine, lactose, low-substituted hydroxypropyl cellulose, and optionally one or more excipients to form a premix;

(b) adding a solvent and optionally a surfactant to the premix formed in Step (a) to form a wet granulation; and

(c) drying the wet granulation using a tray dryer to form dried granules;

(d) optionally milling the dried granules using a low shear mill; and

(e) mixing at least one excipient with the dried granules to form a pharmaceutical composition." Claim 20 is drawn to the method according to claim 19 wherein the low shear mill is a conical screen mill.

Nakajima et al. disclose a method of preparing a pharmaceutical composition comprising fexofenadine, lactose, and a low-substituted hydroxypropyl cellulose, said method comprising: (a) mixing fexofenadine, lactose, low-substituted hydroxypropyl cellulose, and other excipients to form a premix; (b) adding a solvent (purified water) to form a wet mixture; and (c) drying the wet mixture; (d) milling the dried mixture; and (e) mixing an excipient (magnesium stearate) with the dried mixture to form a pharmaceutical composition (see abstract, English Translation, Example/[0010]). It should be noted that the examiner considers the dried mixture to be granules or in granular form, since Nakajima et al. disclose that the mixture was sieved and regulated for particle size (see abstract, English Translation, Example/[0010]).

The difference between applicant's method and the method disclosed by Nakajima et al. is that applicant's does not disclose the use of a try dryer to form dried granules. However, the

use of a specific type of dryer should not affect the composition formed and said use depends on factors like availability and or need.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, to have used the method of Nakajima et al., to prepare a pharmaceutical composition comprising fexofenadine, lactose and hydroxypropyl cellulose to be used as an antihistamine composition, and to use any dryer depending on factors like availability and need.

One having ordinary skill in the art would have been motivated to use the method of Nakajima et al., to prepare a pharmaceutical composition comprising fexofenadine, lactose and hydroxypropyl cellulose to be used as an antihistamine composition, and to use any dryer depending on factors like availability and need.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

June 10, 2005.

ELVIS O. PRICE, PH.D.
PRIMARY EXAMINER